

H1N1 Nasal LAV INFLUENZA VACCINE

Level I

Skill Level: RN, LPN with RN consultation

Definition: Treatment with Nasal H1N1 influenza vaccine (LAV) to help prevent the development and/or reduce severity of influenza in vaccinated individuals. Vaccination with H1N1/LAIV is indicated for healthy individuals 2–49 years of age.

NOTE THAT THIS ORDER IS VALID ONLY FOR 10-1-09 TO 8-30-11

<p>Subjective/Objective:</p> <ol style="list-style-type: none">1. Healthy individual between age 2 and 492. Who do not have one of the following disqualifiers (which are qualifiers for H1N1 vaccine by injection):<ul style="list-style-type: none">• Pregnant• Chronic disorders of the cardiovascular or pulmonary systems requiring regular medical care.• Chronic metabolic diseases such as diabetes, renal dysfunction and hemoglobinopathies• Neuromuscular afflictions as compromise the management of respiratory secretions or increase the risk of aspiration.• Known or suspected immunodeficiency caused by medications or disease, such as; HIV infection, malignancy, leukemia, lymphoma, or who are receiving immunosuppressive therapies• Persons, such as Health Service orderlies, providing assistance to infirmity patients (to protect vulnerable infirmity patients).• Children or adolescents receiving aspirin or salicylates. <p>Do Not Give If:</p> <ul style="list-style-type: none">• Patient is allergic to eggs, chicken, chicken feather, chicken dander.• Patient has had prior allergic reaction to flu vaccine.• Patient with past history of Guillain-Barre syndrome.• Patient with acute febrile illness.	<p>Assessment:</p> <ul style="list-style-type: none">• Patient with appropriate risk factors to warrant current H1N1 Influenza vaccine. <p>Plan:</p> <ul style="list-style-type: none">• Provide the current Vaccine Information Statement (VIS), answering any questions• Patient to read and sign informed consent form. (VAR)• Recheck for any contraindications to vaccine. If contraindications might exist, refer patient case to practitioner.• If no contraindications exist then: administer nasal vaccine.• Each sprayer contains a single dose; approximately one-half of the contents should be administered into each nostril. Refer to the administration diagram (Figure 1) for step-by-step administration instructions.
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APPROVED:

Medical Services Manager

Date

Chief Medical Officer

Date

Steve Sheehan

Medical Director

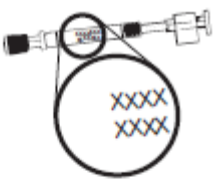
11/6/09

Date

Effective Date: *Nov. 2009*


Revised: October 2009

1




Check expiration date.
Product must be used before the date on sprayer label.

2




Remove rubber tip protector. Do not remove dose-divider clip at the other end of the sprayer.

3




With the patient in an upright position, place the tip just inside the nostril to ensure the vaccine is delivered into the nose.

4




With a single motion, depress plunger **as rapidly as possible** until the dose-divider clip prevents you from going further.

5



Pinch and remove the dose-divider clip from plunger.

6



Place the tip just inside the other nostril and with a single motion, depress plunger **as rapidly as possible** to deliver remaining vaccine.

 **DO NOT INJECT. DO NOT USE A NEEDLE.**

Note: Active inhalation (i.e., sniffing) is not required by the patient during vaccine administration

H1N1 Nasal LAV Influenza Vaccine - Informed Consent

The nasal spray version of the H1N1 vaccine is available for people ages 2-49 who are healthy and not pregnant. Others who may otherwise qualify for H1N1 vaccine should be considered for the injectable H1N1 vaccine.

It is **NOT recommended** for those who may be pregnant or have chronic health conditions.

It is **NOT recommended** for individuals who are 50 years of age or older.

Do Not Give If:

1. Patient is allergic to eggs, chicken, chicken feather, chicken dander.
2. Patient has had prior allergic reaction to flu vaccine.
3. Patient with past history of Guillain-Barre syndrome.
4. Patient with acute febrile illness.
5. Patient is pregnant or possibly pregnant.
6. Patient is 50 years of age or older.
7. Patient has a chronic health condition.
8. Patient is immuno-compromised or on steroids, treatment for Hepatitis C, or other immune modulating medications.

The purpose of H1N1 influenza vaccine is to help prevent the development and/or reduce severity of the current H1N1 pandemic influenza in vaccinated individuals. This is the vaccine recommended by the CDC.

The vaccine is an attenuated (weakened) virus, so it will not cause illness.

Nasal administration of the vaccine stimulates the production of specific antibodies. Protection is afforded only against these strains or closely related strains of influenza.

Adverse reactions:

1. Nasal irritation and rhinitis is sometimes experienced.
2. Less common: fever, malaise, myalgia for 24 - 48 hours may occur very infrequently. (Take acetaminophen)
3. Rare: (presumably allergic) weal, flare, asthma.
4. Very rare: Neurological disorders (may occur within 10 weeks), muscle weakness and paralysis (usually reversible).

I have read the information about influenza vaccine above and on the Vaccine Information Statement "2009 H1N1 LAIV 10/2/09". I have had a chance to ask questions and receive answers. I believe that I understand the benefits and risks of influenza vaccine and request that this vaccine be given to me.

Name _____ SID# _____

Date: _____ Vaccine Lot#: _____

Site of injection: _____

Signature: _____

2009 H1N1 INFLUENZA VACCINE

LIVE, ATTENUATED
(the nasal spray vaccine)

WHAT YOU NEED TO KNOW

Many Vaccine Information Statements are available in Spanish and other languages. See <http://www.immunize.org/vis>.

1 What is 2009 H1N1 influenza?

2009 H1N1 influenza (sometimes called Swine Flu) is caused by a new strain of influenza virus. It has spread to many countries.

Like other flu viruses, 2009 H1N1 spreads from person to person through coughing, sneezing, and sometimes through touching objects contaminated with the virus.

Signs of 2009 H1N1 can include:

- Fatigue
- Fever
- Sore Throat
- Muscle Aches
- Chills
- Coughing
- Sneezing

Some people also have diarrhea and vomiting.

Most people feel better within a week. But some people get pneumonia or other serious illnesses. Some people have to be hospitalized and some die.

2 How is 2009 H1N1 different from regular (seasonal) flu?

Seasonal flu viruses change from year to year, but they are closely related to each other.

People who have had flu infections in the past usually have some immunity to seasonal flu viruses (their bodies have built up some ability to fight off the viruses).

The 2009 H1N1 flu virus is a new virus strain. It is very different from seasonal flu viruses.

Most people have little or no immunity to 2009 H1N1 flu (their bodies are not prepared to fight off the virus).

3 2009 H1N1 influenza vaccine

Vaccines are available to protect against 2009 H1N1 influenza.

- These vaccines are made just like seasonal flu vaccines.
- They are expected to be as safe and effective as seasonal flu vaccines.
- They will not prevent “influenza-like” illnesses caused by other viruses.

- They will not prevent seasonal flu. *You should also get seasonal influenza vaccine, if you want protection from seasonal flu.*

Live, attenuated intranasal vaccine (or LAIV) is sprayed into the nose. **This sheet describes the live, attenuated intranasal vaccine.**

An **inactivated** vaccine is also available, which is given as a shot. It is described in a separate sheet.

The 2009 H1N1 LAIV does not contain thimerosal or other preservatives. It is licensed for people from 2 through 49 years of age.

The vaccine virus is attenuated (weakened) so it will not cause illness.

4 Who should get 2009 H1N1 influenza vaccine and when?

WHO

LAIV is approved for people from 2 through 49 years of age who are not pregnant and do not have certain health conditions (see number 5 below). Groups recommended to receive 2009 H1N1 LAIV first are healthy people who:

- are from 2 through 24 years of age,
- are from 25 through 49 years of age and
 - live with or care for infants younger than 6 months of age, or
 - are health care or emergency medical personnel.

As more vaccine becomes available, other healthy 25 through 49 year olds should also be vaccinated.

Note: While certain groups should not get LAIV – for example pregnant women, people with long-term health problems, and children from 6 months to 2 years of age – it is important that they be vaccinated. They should get the flu shot.

The Federal government is providing this vaccine for receipt on a voluntary basis. However, state law or employers may require vaccination for certain persons.

WHEN

Get vaccinated as soon as the vaccine is available.

Children through 9 years of age should get **two doses** of vaccine, about a month apart. Older children and adults need only one dose.

5 Some people should not get the vaccine or should wait

You should not get 2009 H1N1 LAIV if you have a **severe (life-threatening) allergy** to **eggs**, or to **any other substance in the vaccine**. *Tell the person giving you the vaccine if you have any severe allergies.*

2009 H1N1 LAIV should not be given to the following groups.

- children younger than 2 and adults 50 years and older
- pregnant women,
- anyone with a weakened immune system,
- anyone with a long-term health problem such as
 - heart disease - kidney or liver disease
 - lung disease - metabolic disease such as diabetes
 - asthma - anemia and other blood disorders
- children younger than 5 years with asthma or one or more episodes of wheezing during the past year,
- anyone with certain muscle or nerve disorders (such as cerebral palsy) that can lead to breathing or swallowing problems,
- anyone in close contact with a person with a *severely* weakened immune system (requiring care in a protected environment, such as a bone marrow transplant unit),
- children or adolescents on long-term aspirin treatment.

If you are moderately or severely ill, you might be advised to wait until you recover before getting the vaccine. If you have a mild cold or other illness, there is usually no need to wait.

Tell your doctor if you ever had:

- a life-threatening allergic reaction after a dose of seasonal flu vaccine,
- Guillain-Barré syndrome (a severe paralytic illness also called GBS).

These may not be reasons to avoid the vaccine, but the medical staff can help you decide.

2009 H1N1 LAIV may be given at the same time as most other vaccines. Tell your doctor if you got any other vaccines within the past month or plan to get any within the next month. H1N1 LAIV and seasonal LAIV should not be given together.

6 What are the risks from 2009 H1N1 LAIV?

A vaccine, like any medicine, could cause a serious problem, such as a severe allergic reaction. But the risk of any vaccine causing serious harm, or death, is extremely small.

The risks from 2009 H1N1 LAIV are expected to be similar to those from seasonal LAIV:

Mild problems:

Some children and adolescents 2-17 years of age have reported mild reactions, including:

- runny nose, nasal congestion or cough
- fever
- headache and muscle aches
- wheezing
- abdominal pain or occasional vomiting or diarrhea

Some adults 18-49 years of age have reported:

- runny nose or nasal congestion
- sore throat
- cough, chills, tiredness/weakness
- headache

Severe problems:

- Life-threatening allergic reactions to vaccines are very rare. If they do occur, it is usually within a few minutes to a few hours after the vaccination.
- In 1976, an earlier type of inactivated swine flu vaccine was associated with cases of Guillain-Barré Syndrome (GBS). LAIV has not been linked to GBS.

7 What if there is a severe reaction?

What should I look for?

Any unusual condition, such as a high fever or behavior changes. Signs of a severe allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness.

What should I do?

- **Call** a doctor, or get the person to a doctor right away.
- **Tell** the doctor what happened, the date and time it happened, and when the vaccination was given.
- **Ask** your provider to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form. Or you can file this report through the VAERS website at <http://www.vaers.hhs.gov>, or by calling **1-800-822-7967**.

VAERS does not provide medical advice.

8 Vaccine injury compensation

If you or your child has a reaction to the vaccine, your ability to sue is limited by law.

However, a federal program has been created to help pay for the medical care and other specific expenses of certain persons who have a serious reaction to this vaccine. For more information about this program, call **1-888-275-4772** or visit the program's website at:

<http://www.hrsa.gov/countermeasurescomp/default.htm>.

9 How can I learn more?

- Ask your provider. They can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
 - Call **1-800-232-4636 (1-800-CDC-INFO)** or
 - Visit CDC's website at <http://www.cdc.gov/h1n1flu> or <http://www.cdc.gov/flu>
 - Visit the web at <http://www.flu.gov>



DEPARTMENT OF HEALTH AND HUMAN SERVICES
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